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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/667,237	09/22/2000	Stephen J. Reinl	18696-169197	1339

7590 03/31/2003

Roylance, Abrams, Berdo & Goodman, L.L.P.
1300 19th Street, N.W.
Suite 600
Washington, DC 20036

EXAMINER

FRIEND, TOMAS H F

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 03/31/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/667,237

Applicant(s)

REINL ET AL.

Examiner

Tomas Friend

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-51 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Detailed Action

Change of Art Unit Designation

Please note: The Art Unit location of this application in the PTO has changed from Art Unit 1627 to Art Unit 1639. To aid in matching papers to this application, all further correspondence regarding this application should be directed to **Group Art Unit 1639**.

Change of Examiner

The examiner of this application has changed from Jon Epperson to Tomas Friend.

Status of the Application

Receipt is acknowledged of a reply to a notice to comply with the sequence rules on 06 February 2003 (Paper No. 17). The response is not complete, however, because not all of the occurrences of Gly₄Ser in the claims and specification have been identified by SEQ. I.D. No. Applicants are required to make corrections as part of the response to this office action.

Status of the Claims

Claims 1-51 are pending in the present application and are subject to restriction and election of species requirements.

Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-11 and 49, drawn to libraries of dual-domain nucleic acid molecules and linker molecules or sequences, classified in class 435, digest 37.
- II. Claims 12-15 and 48, drawn to a dual-domain nucleic acid molecule or a linker nucleic acid molecule or sequence, classified in class 536, subclass 23.1.
- III. Claims 16-26 and 44-45 (in part), drawn to a library dual- or multi-domain polypeptide molecules, classified in class 435, digest 35.
- IV. Claims 27-34, and 44-45 (in part), drawn to a dual- or multi-domain polypeptide molecule, classified in class 530, subclass 350.
- V. Claims 35-43, 50, and 51, drawn to methods of generating libraries of dual domain nucleic acids and linkers, classified in class 435, digest 47.
- VI. Claims 46 and 47, drawn to a method of producing a dual domain polypeptide, classified in class 435, subclass 69.1.

The inventions are distinct, each from the other because:

Inventions I-IV and Inventions V and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the compositions of Inventions I and II can both be made by the process of Invention V and the compositions of III and IV can both be made using the process of Invention VI. Also, the compositions of Inventions I-IV can also be made by chemical synthesis on solid supports, for example.

Inventions V and VI are different and patentably distinct methods because they involve different method steps, starting materials, reagents, and/or reaction conditions and/or produce different products or results. For example, the products of Invention V are nucleic acids and the methods involve an amplification step, while the product of Invention VI is a polypeptide and does not include an amplification step.

Inventions I-IV are different and patentably distinct compositions of matter because they have different chemical structures possessing different chemical, physical, and/or biological properties. For example, Inventions I and III are drawn to compositions comprising more than

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one compound (libraries of molecules), while Inventions II and IV are drawn to single molecules. Inventions I and II are drawn to nucleic acids, while Inventions III and IV are drawn to polynucleotides.

Because these inventions are distinct for the reasons given above and

- a. have acquired a separate status in the art as shown by their different classification ;
- b. have different and separately burdensome: manual and/or computer: structure, name and bibliographical searches; and
- c. have divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under CFR 1.17(h).

Election of Species

This application contains claims directed to patentably distinct species of the claimed invention. If applicants elects either of Inventions I or V, applicants are required a species for each of the following A-C:

- A. species of first domain (include whether coding or non-coding and binding properties, if any),
- B. species of second domain (include whether coding or non-coding and binding properties, if any), AND
- C. species of repeated pattern of degenerate repeated triplet nucleotides.

If applicants elect Invention II, applicants are required an ultimate species (i.e. nucleotide sequence) of dual-domain nucleic acid molecule and identify each domain and linker sequence.

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If applicants elect Invention III, applicants are required a species for each of the following A-D:

- A. ultimate species of x,
- B. ultimate species of y,
- C. species of D for each D (x species), AND
- D. species of repeated pattern of degenerate repeated triplet nucleotides.

If applicants elect either of Inventions IV or VI, applicants are required an ultimate species (i.e. amino acid sequence) of polypeptide and identify each domain and linker sequence.

The species are distinct, each from the other, because they have different structures with different chemical, physical, and/or pharmacological properties. Therefore, different issues of enablement and patentability apply to each species and each species represents patentably distinct subject matter.

Applicants are required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicants traverse on the ground that the species are not patentably distinct, applicants should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicants are advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Tomas Friend**, telephone number **(703) 308-4548**. The examiner's schedule is normally four, ten-hour days per week that includes Saturdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2742.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist at (703) 308-1235.

Tomas Friend, Ph.D.
24 March 2003



ANDREW WANG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600